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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
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RE: Docket No. 85N-0214 (180-Day Generic Exclusivity Proposed Rule)

Dear Sir/Madam:

Bristol-Myers Squibb Company submits these comments on FDA's proposed rule regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, published at 64 Fed. Reg. 42,873 (Aug. 6, 1999) ("Proposed Rule").

I. THE PROPOSED RULE IGNORES CHEVRON AND COURT DECISIONS FINDING THE 180-DAY EXCLUSIVITY PROVISION UNAMBIGUOUS

The Proposed Rule results from court decisions striking down the successful defense requirement which FDA had added to the statutory requirements for 180-day generic drug exclusivity. Much of the Proposed Rule is devoted to FDA's claim that it is based on the presumed legislative purpose of minimizing delay in getting generic products to market. Proposed Rule, 64 Fed. Reg. at 42,874-75, 42,877-78, 42,880-84. With respect to the statutory language itself, FDA offers a single sentence, which claims that the statutory language describing eligibility for 180-day generic drug exclusivity is ambiguous. Id. at 42,875.

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A. Chevron

FDA's excessive focus on its conception of Hatch-Waxman's legislative purpose and minimal recourse to the statutory language reverses the proper approach for an administrative agency charged with interpreting a statute. The familiar Chevron starting point for an agency is the statutory language, which must be followed to the letter if unambiguous (Chevron step one), or reasonably interpreted, if not (Chevron step two). Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984); Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1067 (D.C. Cir. 1998). Where "the language of a provision . . . is sufficiently clear in its context and not at odds with the legislative history, . . '[there is no occasion] to examine the additional considerations of "policy" . . . that may have influenced the lawmakers in their formulation of the statute.'" Rodriguez v. United States, 480 U.S. 522, 526 (1987) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 214 n.33 (1976)).

Courts which have reviewed the statutory requirements for 180-day exclusivity have found them unambiguous. See, e.g., Mova, 140 F.3d at 1068 ("the FDA cannot point to any particular ambiguity in the words of [the statute] that permits it to interpolate its 'successful defense' requirement"); Granutec, Inc. v. Shalala, 1998 U.S. App. LEXIS 6685, at *20 (4th Cir. 1998) (the 180-day requirements are "clear and conclusive"); Mova (Dist. Ct.), 955 F. Supp. 128, 130-31 (D.D.C. 1997) ("The language of the statute . . . is plain and unambiguous"); Inwood Labs. v. Young, 723 F. Supp. 1523, 1525 (D.D.C. 1989) (vacated as moot, 43 F.3d 712 (D.C. Cir. 1989)) ("[t]he statute is clear"). In each case, FDA lost its claim that the standards for 180-day eligibility are ambiguous, despite having briefed the issue in much greater detail than its

single sentence in the Proposed Rule. Given FDA's experiences in court, the Agency's brief assertion here that the statute is ambiguous (and failure to explain why) is particularly surprising.

B. Granutec

The two circuit decisions striking down the successful defense requirement, Granutec and Mova, took slightly different approaches. Both found that the statutory requirements for 180-day eligibility are unambiguous, and that the successful defense requirement was therefore impermissible because it added a new requirement not found in the statute.

In Granutec, the Fourth Circuit, "[h]aving found the exclusivity requirements embodied in the statutory language . . . clear and conclusive, [found itself] bound to hold invalid any attempt to alter the terms of that statute." 1998 U.S. App. LEXIS 6685, at *20. Given the statute's clarity, Granutec, citing Chevron, refused to consider the legislative history and policy goals of Hatch-Waxman, and simply struck down the successful defense requirement. Id. at *19-*20. Separately, Granutec found "the date of a decision of a court" to be an ambiguous term and thus deferred to FDA's interpretation that the decision could be one other than in the case involving the first Paragraph IV certifier. According to the court, FDA's interpretation largely avoided "generic capture," a result which "could not have been contemplated by Congress." Id. at *27. To the extent the generic capture problem persists despite FDA's "court" interpretation, the Granutec court found that it "arises from the manner in which Congress drafted the exclusivity mechanism, and, as such, the remedy lies with Congress." Id. at n.3.

C. Mova

The D.C. Circuit in Mova agreed that the clarity of the statutory requirements for 180-day eligibility made the successful defense requirement impermissible. Unlike the Fourth Circuit in Granutec, however, the D.C. Circuit was willing to entertain arguments that the statute's purpose is undermined by a literal reading, i.e., that the statute as written leads to the allegedly absurd result that sales of subsequent ANDAs can be blocked by the failure of the first applicant's 180 days to begin. For the D.C. Circuit, if FDA could prove that a literal reading of the statute produces an absurd result, it would be permissible for the Agency to modify the 180-day exclusivity requirements in a way that would "deviate no further from the statute than is needed to protect congressional intent." Mova, 140 F.3d at 1068.

FDA, however, was unable to persuade the Mova court that the statute as written leads to any absurd result. FDA advanced two "absurd result" scenarios, and Mylan Pharmaceuticals added a third. In the first scenario, the first ANDA applicant is never sued (thus avoiding any court decision start to its 180 days) and chooses, alone or in collusion, not to market (thus avoiding a commercial marketing start to its 180 days). The Mova court held that this was insufficient to justify the broad "successful defense" requirement, and noted that a narrower requirement -- that the first applicant simply be sued -- would solve the problem. Id. at 1070-71. Even that might not be the narrowest solution, said the court, as Congress may have wanted to reward first applicants ingenious enough not to be sued, in which case FDA might require that such applicants market within a certain time period. Id. at 1071 n.11.

FDA's second "absurd result" scenario was that first ANDA applicants who lose their suits will not pull either 180 day trigger, forcing subsequent applicants to wait until patent expiration before they can market. The Mova court also found this scenario insufficient to justify the successful defense requirement, because FDA's "housekeeping" regulation, which requires applicants who lose their suits to change from a Paragraph IV to Paragraph III certification, offers a more narrow solution. Id. at 1071.

The Mova court deemed the third "absurd result" scenario a "compelling argument" for the successful defense requirement. Id. at 1072. In this third scenario, a subsequent applicant does a better job than the first applicant of designing around the pioneer's patent, such that the first applicant is sued but the second is not. Although this "admittedly produces a strange result" where the second applicant must wait, perhaps years, for the first applicant's suit to conclude, as with the first two scenarios the Mova court was:

> "not persuaded that this [scenario] suffices to show that a literal reading of the statute leads to results manifestly inconsistent with the intent of Congress. . . . [I]t is not inconceivable that Congress meant what the statute says, i.e., that the second applicant would have to wait for the first lawsuit to finish. . . . The successful defense requirement may therefore have the effect of allowing many ANDA applicants to sell their products without regard to the exclusivity period, a result that Congress might not have intended."

Id. at 1071-72. Consequently, Mova found that while the third scenario presented a real problem, "the successful defense requirement is too blunt an instrument to solve it." Id. at 1074. Because none of the three scenarios produced absurd results justifying the successful defense requirement, it was rejected by the Mova court.

In its discussion of the third scenario, the Mova court also agreed with Granutec that the court decision trigger can be satisfied by decisions in suits involving subsequent Paragraph IV applicants, noting that this might be a way for second applicants to get to market before the first applicant's suit terminates. Id. at 1072-73. In particular, a second applicant that is not sued could request a declaratory judgment of non-infringement, which could satisfy the court decision trigger and begin the first applicant's 180 days. However, the court also noted that this strategy may not work because second applicants might be unable to meet the constitutional case or controversy requirement, especially if the patent holder disclaims any intention of bringing suit (as discussed at pp. 14-15 below, the recent Teva case seems to resolve this issue). Id. at 1073.

In conclusion, Granutec and Mova found the 180-day statute unambiguous. Their strict holdings left FDA little maneuvering room to promulgate new requirements for 180-day exclusivity. Yet, for reasons unclear, that is precisely what the Agency has done.

II. THE PLAIN LANGUAGE OF THE STATUTE REQUIRES A SEPARATE 180-DAY EXCLUSIVITY PERIOD FOR EACH LISTED PATENT

FDA proposes that where there are multiple patents claiming the listed drug product, the first ANDA making a Paragraph IV certification to any one of those patents will be the only ANDA eligible for 180-day exclusivity. 64 Fed. Reg. at 42,875-76. The statute, however, requires granting a separate 180-day exclusivity for each listed patent.

Pursuant to Chevron, the first question is whether the statute addresses whether a 180-day exclusivity period should be awarded for each patent claiming the listed drug (i.e.,

patent-by-patent exclusivity) or whether there is only one 180-day period per drug (product-by-product exclusivity). The answer is that the plain terms of the statute require separate 180-day periods for each patent claiming the listed drug. In the court decision trigger, the statute provides that a subsequent ANDA will only be blocked until 180 days after a decision on "the patent which is the subject of the certification." FFDCA § 505(j)(5)(B)(iv). A decision on another patent will not do. Which patent is "the subject of the certification" is determined by reference to section 505(j)(2)(A)(vii), which likewise demands a patent-by-patent approach by requiring a certification "with respect to each patent which claims the listed drug." (Emphasis added.) Numerous court decisions confirm this longstanding interpretation. See, e.g., Eli Lilly and Co. v. Medtronic, Inc. 496 U.S. 661, 677 (1990); Mova, 140 F.3d at 1062; Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997); Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130, 1132 (Fed. Cir. 1995). The statute thus unambiguously provides for patent-by-patent exclusivity.

Recognizing the statute's clarity, FDA's current regulations also provide for patent-by-patent exclusivity. The regulations state that if an application contains a Paragraph IV certification to "a relevant patent" and an ANDA was previously submitted with a Paragraph IV certification to "the same patent," then the subsequent applicant must wait until 180 days after a court decision on "the relevant patent." 21 C.F.R. § 314.107(c). Thus, FDA has recognized the statutory identity among the patent certified to by a subsequent ANDA applicant, the patent certified to by a previous ANDA applicant, and the patent which creates 180-day exclusivity. See 21 U.S.C. § 355(j)(5)(B)(iv). A separate 180-day period therefore springs from each patent,

because the statute requires a 180-day wait only from a subsequent applicant which Paragraph IV certifies to the relevant patent, not from Paragraph IV certifiers to other patents on the drug (the extra-statutory result flowing from a product-by-product approach).

The Proposed Rule abandons FDA's established policy in favor of a product-by-product approach. Rather than offer an explanation, FDA proceeds as if the August 1999 Proposed Rule is the first time it has considered this issue regarding interpretation of a 1984 law. 64 Fed. Reg. at 42,875-76. Because FDA failed to provide "a reasoned analysis indicating that prior policies are being deliberately changed, not casually ignored," the Proposed Rule is flawed, and should be re-promulgated. Simmons v. Interstate Commerce Comm'n, 829 F.2d 150, 156 (D.C. Cir. 1987) (quoting Greater Boston Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir. 1970)).

Although brief, FDA's argument appears to be, once again, that the statute is ambiguous, since the Agency agrees that "the statute would support"[1] patent-by-patent exclusivity, but nonetheless rejects it. Although FDA fails to point to any ambiguity allowing it to disregard the statute's plain terms, the Agency may believe that the identity described above (the patent certified to by the subsequent applicant = the patent certified to by the previous applicant = the patent which triggers the 180 days) is not the unambiguous result required by the statute. If that is FDA's belief, it is incorrect.

The 180-day provision explicitly creates the three-way identity by making three references to patent certifications. The first is to the subsequent ANDA's Paragraph IV

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[1] 64 Fed. Reg. at 42,875.

certification, which, by definition, would be to a particular patent. 21 U.S.C. § 355(j)(5)(B)(iv). The second reference is that the previous ANDA contains "such a certification," which is also, of course, a certification to a particular patent. Id. The third references "the patent which is the subject of the certification" that the previous and subsequent applicants made, making clear the identity among the three. Id. at (II).

FDA's contrary product-by-product reading would rewrite the statute, because it would allow any patent, not just "the patent which is the subject of the certification" to trigger the sole 180-day period for a product. Moreover, by rewriting the statute FDA would make the statute incomprehensible and impossible to administer. For example, if multiple patents are certified to, which patent is "the patent which is the subject of the certification" which triggers the 180 days?[2] The statute provides no decision rule to break this extra-statutory impasse, the absurdity of which is alone sufficient to condemn the product-by-product interpretation. See, e.g., United States v. X-Citement Video, Inc., 513 U.S. 64, 69-70 (1994) (statutes should be construed to avoid absurd results). Rather than rewrite the statute to create absurdity, FDA should stick with the as-written statute's requirement of patent-by-patent exclusivity.

Other provisions of Hatch-Waxman reinforce the patent-by-patent approach of 180-day exclusivity. See Mova , 140 F.3d at 1067-68 (in construing a statute, one must look to the provisions of the law as a whole). For example, each individual patent covering the listed drug, not one patent per listed drug, must be submitted for listing in the Orange Book. 21 U.S.C.

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[2] The Proposed Rule itself highlights this inevitable problem with the product-by-product interpretation when it provides that the 180 days shall begin after a court decision on "the relevant patent" without defining what "the relevant patent" is. See 64 Fed. Reg. at 42,885-86.

§ 355(b)(1). Similarly, the effect of patents on FDA approval is dealt with patent-by-patent, including separate 30 month periods for each patent which is litigated. 21 U.S.C. § 355(j)(5)(B)(iii). Moreover, Congress knew how to enact product-by-product language when that was its intent. The patent term restoration statute, which authorizes only one patent term restoration per product, is an example where Congress did enact product-by-product language. 35 U.S.C. § 156(c)(4). Congress therefore knew how to codify a product-by-product approach in Hatch-Waxman when it wanted to, and the lack of any such language in the 180-day provision reinforces still further the conclusion that Congress intended 180-day exclusivity to be patent-by-patent.

The preceding is Chevron step one analysis based solely on the plain terms of the statute. Because the statute's terms unambiguously require patent-by-patent exclusivity, other considerations cannot be addressed. Rodriguez, 480 U.S. at 526; Granutec, 1998 U.S. App. LEXIS 6685, at *19-*20. FDA's only option would be to show that the statute creates absurd results, Mova, 140 F.3d at 1068, but the Agency does not attempt to make such a showing. Instead, FDA asserts that patent-by-patent exclusivity (1) might delay generic marketing for a "substantial period of time;" and (2) would be "virtually unworkable in its complexity." 64 Fed. Reg. at 42,875-76. Neither reason demonstrates absurd results, however. Mova found that delay in generic marketing caused by 180-day exclusivity is not a result sufficiently absurd to justify abandoning the statute, and administrative convenience does not warrant flaunting a statute's plain terms. Mova, 140 F.3d at 1070-74; Western Nat'l Mut. Ins. Co. v. Commissioner of Internal Revenue, 65 F.3d 90, 93 (8th Cir. 1995) (administrative convenience cannot override

unambiguous statutory meaning). FDA has therefore offered no legitimate basis for adopting its proposed product-by-product approach.

III. THE PROPOSED "TRIGGERING PERIOD," LIKE THE INVALIDATED SUCCESSFUL DEFENSE REQUIREMENT, CANNOT BE RECONCILED WITH THE LANGUAGE OF THE STATUTE

FDA proposes to replace the invalidated successful defense requirement with a new condition on 180-day exclusivity: the "triggering period." The Proposed Rule does not explain which part of the statute authorizes the triggering period. Instead, the triggering period is justified on the policy argument that Hatch-Waxman's goal is to limit the delay in marketing of subsequent generic products that a previous applicant's 180-day exclusivity may cause. 64 Fed. Reg. at 42,877.

The starting point for the triggering period is the footnoted dictum in Mova mentioning the concept as a potential solution to the scenario where subsequent applicants must wait because the first applicant is not sued:

> An alternative might be to prescribe a period within which a first applicant who has not been sued must bring his product to market in order to benefit from the exclusivity period.

Mova, 140 F.3d at 1071 n.11. The Proposed Rule would expand the Mova concept to all applicants eligible for 180-day exclusivity, not just those who are not sued. Thus, the triggering period generally would start for a first applicant upon tentative approval of a subsequent ANDA when the subsequent ANDA could receive final approval but for the first applicant's 180-day exclusivity. 64 Fed. Reg. at 42,877. If the first applicant's 180-day exclusivity is not triggered during the triggering period (also 180 days in length), the first applicant would lose its 180-day

exclusivity entitlement. Id. However, the start date for the triggering period could not begin earlier than expiration of the first applicant's 30-month litigation period (if the first applicant is sued), an injunction prohibiting marketing of the first applicant's product, or exclusivity periods protecting the pioneer product. Id.

A. The Statute is Unambiguous

The unambiguous statute does not authorize the triggering period proposed by FDA. "By expressly including certain requirements in the statue to the exclusion of all others, Congress presumably intended that the statutory requirements would comprise the full measure of eligibility [for 180-day exclusivity]." Granutec, 1998 U.S. App. LEXIS 6685, at *18. The triggering period adds a novel, extra-statutory requirement that the first applicant must trigger its 180-day exclusivity within a restrictive 180-day window. The statute imposes no such restriction on the first applicant, and presents no ambiguity which would allow the interpolation of such a requirement. Like the successful defense requirement, the triggering period is an invalid addition to the statutory requirements for 180-day exclusivity and should be abandoned.

Nor is the triggering period somehow justified by the Mova footnote. The Mova dictum was limited to first applicants which have not been sued. Such applicants can market without fear of infringing, but have chosen not to, and a triggering period would force them to use or lose the 180-day exclusivity. Unlike FDA, however, Mova did not propose using the triggering period to force litigating first applicants into the Hobson's choice of losing their 180-

day exclusivity or using it and thereby risking substantial damages.[3] Indeed, the Proposed Rule's expansion of the Mova footnote runs contrary to the separate Mova finding that "it is not inconceivable that Congress meant what the statute says, i.e., that the second applicant would have to wait for the first lawsuit to finish." 140 F.3d at 1072. Consequently, there can be no contention that the Mova footnote constituted an advisory endorsement which somehow inoculated the proposed triggering period from the rigors of basic Chevron administrative law.

B. FDA's Policy Argument is Unavailing

FDA's claim that the policy of speeding generics to market justifies the Proposed Rule also fails. As Mova explains, the only way for FDA to justify an additional requirement like the triggering period is to show that the statute as written leads to an absurd result, but the Agency makes no such showing here. Rather, having failed to persuade any court of absurd results justifying FDA's intervention, the Agency abandons the statutory text and skips directly to policy. If enacted as proposed, this failure to comply with Chevron would seem destined to defeat upon judicial review. Moreover, FDA's policy argument ignores the fact that the statute already solves FDA's concerns, rendering the triggering period unnecessary.

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[3] The Proposed Rule thus reverses FDA's previous position that "[i]t serves the public interest to permit a prudent ANDA holder in that situation to stay off the market until the litigation is resolved, thereby minimizing potential damages." Abbreviated New Drug Application Regulations, Proposed Rule, 54 Fed. Reg. 28,872, 28,894 (July 10, 1989). This despite the fact that the Mova court deemed FDA's previous stance a "plausible explanation." 140 F.3d at 1070.

C. The Statute Already Solves FDA's Concerns

There is no need for FDA to delve into the Hatch-Waxman congressional compromise and divine a new balance. The plain terms of the statute fully resolve FDA's concerns. The Proposed Rule already recognizes that "a decision of a court" need not be a decision in litigation involving the previous ANDA applicant. 64 Fed. Reg. at 42,879-80. As Granutec and Mova found, this interpretation in large part eliminates any concern that subsequent ANDAs may be forever blocked by the first ANDA's 180-day exclusivity, because litigation involving subsequent ANDAs is sufficient to pull the court decision trigger and thus prevent any undue delay in their approval. 1998 U.S. App. LEXIS 6685, at *27; 140 F.3d at 1073.

Mova's sole remaining concern was that this solution might not work in the case of a subsequent ANDA applicant which is not sued, because it might not be able to obtain a decision sufficient to satisfy the court decision trigger. That concern has since been resolved. Teva Pharmaceuticals, USA, Inc. v. United States F.D.A., 182 F.3d 1003 (D.C. Cir. 1999). In Teva, a subsequent generic which had not been sued brought a declaratory judgment action which was dismissed for lack of case or controversy because the pioneer disclaimed any intent to sue. Id. at 1006. The D.C. Circuit found that the statute could be interpreted to construe such a decision as a "decision of a court" sufficient to trigger 180-day exclusivity. Id. at 1007-12. Under this interpretation, it would appear that a subsequent applicant would always be in a position to obtain a court decision triggering the previous applicant's exclusivity.

The Proposed Rule took the position that dismissals like that in Teva would not qualify as a court trigger for 180-day exclusivity. 64 Fed. Reg. at 42,881. It is assumed that

FDA has reevaluated this position as a result of the recent Teva decision. Not only has an appellate court found that the statute permits dismissals of patent declaratory judgment actions to be court decisions sufficient to trigger 180-day exclusivity, FDA's adoption of the court's reasoning would provide a solution to its concerns about indefinite delay in generic marketing.

As a result of Mova and Teva, no subsequent ANDA can be indefinitely delayed by a previous applicant's 180-day exclusivity. Because the status quo already resolves FDA's concerns, there appears little need (let alone a statutory basis) for the Proposed Rule's extra-statutory triggering period.

IV. DISMISSALS

FDA proposes that a dismissal, with or without prejudice, of Paragraph IV litigation without a court decision on the merits of the patent will end the 30-month stay of ANDA approval. 64 Fed. Reg. at 42,881. FDA explains that the 30-month period is to allow innovator companies a chance to enforce their patents, but that such concerns are not implicated when the suit is dismissed by settlement or licensing agreement, or because the patent owner or NDA holder have determined not to pursue litigation. Id.

This proposal would cause adverse results probably not intended by the Agency, and should therefore be clarified to indicate that the 30-month period will not end if the dismissal is against the innovator's wishes and the innovator is appealing the dismissal, or until the time for appeal has run. This would simply reaffirm FDA's current interpretation of what a "decision of a court" is for purposes of Paragraph IV litigation. 21 C.F.R. § 314.107(e). In the same vein, a dismissal for a minor procedural defect which can be readily remedied by refiling the suit, or

resulting from a judicial conclusion that the Paragraph IV certification was defective, should not end the 30-month period. Finally, to the extent FDA enacts its triggering period (a result BMS opposes, as above), it should clarify that dismissal based on settlement with a subsequent certifier will not start the triggering period. Otherwise, an innovator might not settle with subsequent certifiers, even if they do not wish to continue litigation, for fear of starting the triggering period.

V. CONCLUSION

The Proposed Rule repeats the mistakes of the successful defense requirement. It ignores the courts, which have made clear that the statute is unambiguous, in favor of new, extra-statutory constructions justified on a terse claim of statutory ambiguity and repetitive recourse to supposed statutory policies. The plain terms of the statute, however, require patent-by-patent exclusivity, do not authorize a triggering period, and already resolve FDA's policy concerns. FDA's approach should be modified to take the plain terms of the statute into account.

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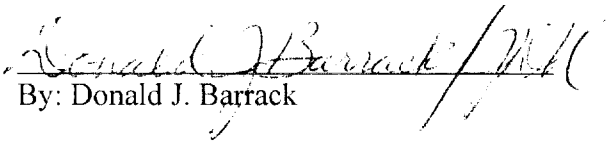

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